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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/750,473	12/29/2000	Trevor Percival Castor	TC-1	6580

7590 11/06/2003  
Trevor P. Castor  
Aphios Corporation  
3-E Gill Street  
Woburn, MA 01801

EXAMINER

THEISEN, MARY LYNN F

ART UNIT	PAPER NUMBER
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1732

DATE MAILED: 11/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/750,473

Applicant(s)

CASTOR, TREVOR PERCIVAL

Examiner

Mary Lynn F. Theisen

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 13-20 is/are rejected.
- 7) ☒ Claim(s) 12 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____.  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1,2,11 and 16-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Smith (4,582,731).

3. Smith discloses dissolving a polymer in a supercritical fluid and depressurizing to form particles (column 2, lines 8-11; column 3, lines 6-10). Some particles have an average size of 0.3 microns (column 12, lines 35-40). Smith also teaches how to vary the size of the particles (see claim 13). With respect to the apparatus Smith (Fig. 4) has an admixture vessel (inside 214), an orifice (104) and a depressurization vessel (218). The type of material used in the apparatus is not deemed to make it patentably distinct from the prior art.

4. Claims 16-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Castor.

5. Castor discloses an admixture vessel (15), orifice nozzle (33a) and depressurization vessel (17).

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 1-11 and 13-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Castor in view of Fischer et al.

8. Castor dissolves a lipid in a supercritical fluid and depressurizes to form particles. The lipid may include a bioactive ingredient (column 3, lines 46-47). Fischer shows that supercritical fluids can dissolve polymers, lipids, waxes and lecithins (column 6, line 67 through column 7, line 1) and the desirability of a particle having a polymer carrier and bioactive material (Example 1). It would have been obvious to one of ordinary skill in the art to substitute a polymer for the lipid of Castor because Fischer indicates that supercritical fluids will dissolve polymers and that the resultant product (polymer/bioactive) is desirable.

9. Claims 1-11 and 13-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shine in view of Smith (4,582,731).

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Shine discloses dissolving polymer in a supercritical fluid and depressurizing to form particles. A bioactive material may be included in either the polymer or supercritical fluid. The polymers include poly-glycolic acid and poly-lactic acid. Shine does not indicate the size of the particles formed, however, the claimed size would have been obvious to one of ordinary skill in the art because Smith (described above) teaches the size limitation and how to vary it in the same type of process.

***Allowable Subject Matter***

10. Claim 12 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

11. The following is a statement of reasons for the indication of allowable subject matter: The prior art does not suggest PVA, PBS or liquid nitrogen be in the depressurizing chamber.

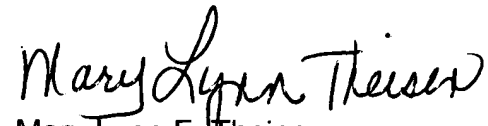
***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary Lynn F. Theisen whose telephone number is 703-308-2312. The examiner can normally be reached on Thursday and Friday 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Colaianni can be reached on 703-305-5493. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.



Mary Lynn F. Theisen  
Primary Examiner  
Art Unit 1732

mlt